Prescription Drug User Fees

Unapproved Drug Workshop

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PDUFA - 3 Kinds of Fees

- Application Fees (one time - when human drug application submitted)
- Product Fees (annual)
- Establishment Fees (annual)

Fees

App Type	2007 Fee
IND	0
NDA w clinical data (CD)	$896,200
NDA: no CD	$448,100
Supp: w CD	$448,100
Supp: no CD	0

Collection of Fees

- Application Fees
  - No invoice; pay fee to Mellon Bank in Pittsburgh when application submitted; either need to have a waiver granted or must pay the fee when application submitted.
- Product and Establishment Fees
  - - Invoiced in August each fiscal year; payment due October 1
  - -“Clean up” bill in November

Bundling Policy and Definition of Clinical Data

- Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004)
  - what may be submitted in an application
  - what may be submitted in a separate application
  - what may be submitted as a supplement
  - provides a uniform definition of the term “clinical data” for user fees
  - provides a level playing field for industry

Human Drug Application?

- "Human Drug Applications" assessed fees:
  - 505(b)(1) applications and certain biologics submitted under section 351 of the PHA
  - Most 505(b)(2) applications
  - b2's assessed fees if
    - new entity or
    - new "indication for a use" broadly interpreted
  - Not generic drug applications (505(j))

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505(b)(1) vs 505(b)(2)

- Key difference – who owns the data?
  - 505(b)(1) applications
    - you own or have the right of reference to data required for approval
  - 505(b)(2) applications
    - you do not own or do not have the right of reference to data required for approval

Fee paying 505(b)(2)?

- Examples of new “indication for a use” include any change from application previously approved under section 505(b):
  - new indication
  - new patient population
  - new dosing regime
  - statements comparing to another product

- Once a 505(b)(2) application for a particular product is approved, subsequent applications will be submitted under 505(j) and will not be assessed fees under PDUFA

Human Drug Application?

- "Human Drug Applications" do not include:
  - OTC Monograph Drugs (vs NDA OTC drugs)
  - ANDA's (a.k.a. 505(j)'s)
  - Investigational new drugs applications (INDs)
  - Drug Master Files (DMFs)
  - CBER carve outs (e.g., crude allergenic extracts)
  - Certain 505(b)(2)'s (those that are not new entities or new "indications for a use")
- Exemptions
  - Government applications IF not for commercial use
  - Orphan Exemption

Waivers - 736(d) of the FDC Act

- Small Business
- Public Health
- Barrier to Innovation
- Fees Exceed the Cost

Small Business

- First human drug application for you and your affiliates
- You and your affiliates have under 500 employees
- Full application fee waiver!

Public Health – Barrier to Innovation

- Benefits public health or is innovative
- For example: priority review, NME, or fast track
- Also consider treatment alternatives
- Waiver “is necessary” or “because of limited resources”

Fees Exceed the Cost

- All fees paid v. all costs!
- Guidance Document

  www.fda.gov/cder/pdufa/fecgud99.pdf
- Pay up front, but ….

Annual Fees -- Products

- The product must be
  - subject to an approved human drug application
  - in the active portion of the Orange Book
  - not the same as another product
  - not an OTC
- The applicant must have an application or supplement pending after 9/1/92.
- FY 07 fee = $49,750

Annual Fees -- Establishments

- The applicant, not the establishment owner, is responsible for the establishment fee
- Who must pay?
  - an applicant with applications or supplements pending after 9/1/92, who manufactures a *prescription drug product* in *final dosage form*
  - only if product is assessed a product fee
  - may share the establishment fee with others who use same manufacturing facility
- FY 07 Fee = $313,100

Waiver Process

- Written request
- Courier to: Michael Jones, FDA/CDER/ORP, Rockwall 2, Suite 1101, 5515 Security Lane, Rockville, MD 20852
- Refer to pages 22 - 24 in FDA's Interim Guidance Document for Waivers of and Reductions in User Fees
- Call me once you have a draft and before you send in the request: 301-594-2041.

www

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http://www.fda.gov/cder/pdufa/default.htm

FDA

http://www.fda.gov/oc/pdufa/default.htm